



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Dennis L. Panicali et al.

Application No.: 10/660,369

Group No.: 1614

Filed: 09/11/2003

Examiner: To be assigned

For: TRANSDUCED NEOPLASTIC CELL PREPARATIONS ABLE TO EXPRESS T-CELL COSTIMULATORY MOLECULES B7.1, ICAM-1 AND LFA-3 AND INDUCE IMMUNOSTIMULATORY PROPHYLACTIC AND THERAPEUTIC ANTI-TUMOR EFFECTS IN VIVO

## MAIL STOP AMENDMENT

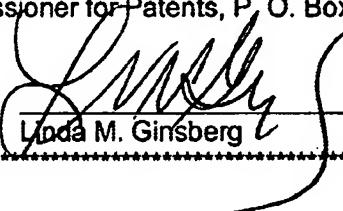
Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

\*\*\*\*\*  
CERTIFICATE OF MAILING

I hereby certify that this correspondence is, on the date shown below, being: deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Date: October 26, 2004  
Linda M. Ginsberg\*\*\*\*\*  
Sir:

## INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §§1.56 and 1.97, Applicants herewith submit the publications and/or patents shown on the attached forms PTO/SB/08a and b, for consideration by the Examiner in connection with the examination of the above-identified patent application.

## I. REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

(1) within three (3) months of the Filing Date or before the mailing date of the First Office Action on the merits; or

(2) within three months of the mailing date of the PCT International Search Report; or

- (3) after the period defined in (1) but before the mailing date of a **Final Rejection or Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or
- (4) after the mailing date of a **Final Rejection or Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

It is respectfully requested that each of the documents shown on the attached form(s) PTO/SB/08a and b be made of record in this application. Copies of these documents (CHECK ONE):

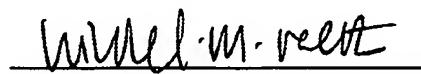
- are enclosed herewith; and
- have been cited in the parent application, and are thus not being resubmitted herein.

Early examination and allowance of the present application are respectfully solicited.

#### FEE AUTHORIZATION

Should any fees associated with the submission be required, the Commissioner is authorized to charge the missing fee to our Deposit Account No. 50-0850. Any overpayments should be credited to said Deposit Account.

Respectfully submitted,

  
Ronald I. Eisenstein (Reg. No. 30,628)  
Nicole L.M. Valtz (Reg. No. 47,150)  
NIXON PEABODY LLP  
100 Summer Street  
Boston, MA 02110  
(617) 345-6054

Date: October 26, 2004



OCT 28 2001

PTO/SB/08a (08-03)

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

**Complete If Known**

Application Number	10/660,369
Filing Date	09/11/2003
First Named Inventor	Dennis L. Panicalli
Art Unit	1614
Examiner Name	To be assigned
Attorney Docket Number	700953-544440

She

1

U. S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			

**Examiner  
Signature**

Date  
Considered

**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO				Complete If Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/660,369
(Use as many sheets as necessary)				Filing Date	09/11/2003
				First Named Inventor	Dennis L. Panicali
				Art Unit	1614
				Examiner Name	To be assigned
Sheet	1	of	2	Attorney Docket Number	700953-54440

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	C1	BJARNE BOGEN ET AL., "Processing and Presentation of Idiotypes to MHC-Restricted T Cells," <i>Intern. Rev. Immunol.</i> , Vol. 10, p. 337-355, (1993).		
	C2	BJARNE BOGEN, "Idiotope-specific T cell clones that recognize syngeneic immunoglobulin fragments in the context of class II molecules," <i>Eur. J. Immunol.</i> , Vol. 16, p. 1373-1378, (1986).		
	C3	STEPHANIE A. CAMACHO ET AL., "A key role for ICAM-1 in generating effector cells mediating inflammatory responses," <i>Nature Immunology</i> , Vol. 2 (No. 6), p. 523-529, (2001).		
	C4	MICHAEL CROFT ET AL., "Naive Versus Memory CD4 T Cell Response to Antigen," <i>Journal of Immunology</i> , Vol. 152, p. 2675-2685, (1994).		
	C5	MATTHEW J. DEETHS ET AL., "ICAM-1 and B7-1 provide similar but distinct costimulation for CD8+ T cells, while CD4+ T cells are poorly costimulated by ICAM-1," <i>Eur. J. Immunol.</i> , Vol. 29, p. 45-53, (1999).		
	C6	KYRIAKI DUNUSSI-JOANNOPOULOS ET AL., "Irradiated B7-1 Transduced Primary Acute Myelogenous Leukemis (AML) Cells Can Be Used as Therapeutic Vaccines in Murine AML," Vol. 87 (No. 1), p. 2938-2946, (1996).		
	C7	KARL ERIK HELLSTROM ET AL., "On the Role Costimulation in Tumor Immunity," <i>Annals New York Academy of Sciences</i> , Vol. 690, p. 225-230, (1993).		
	C8	JAMES W. HODGE ET AL., "A Triad of Costimulatory Molecules Synergize to Amplify T-Cell Activation," <i>Cancer Research</i> , Vol. 59, p. 5800-5807, (November 15, 1999).		
	C9	KAZUNORI KATO ET AL., "Gene Transfer of CD40-Ligand Induces Autologous Immune Recognition of Chronic Lymphocytic Leukemia B Cells," <i>J. Clin. Invest.</i> , Vol. 101 (No. 5), p. 1133-1141, (March, 1998).		
	C10	DAVID N. LIEBOWITZ ET AL., "Costimulatory approaches to adoptive immunotherapy," <i>Current Opinion in Oncology</i> , Vol. 10, p. 533-541, (1998).		
Examiner Signature				Date Considered

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete. Including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO				<i>Complete if Known</i>	
				Application Number	10/660,369
				Filing Date	09/11/2003
				First Named Inventor	Dennis L. Panicali
				Art Unit	1614
				Examiner Name	To be assigned
Sheet	2	of	2	Attorney Docket Number	700953-54440

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	C11	EDUARDO PARRA ET AL., "The Role of B7-1 and LFA-3 in Costimulation of CD8+ T Cells," The Journal of Immunology, Vol. 158, p. 637-642, (1997).			
	C12	JOACHIM L. SCHULTZE ET AL., "Follicular lymphomas can be induced to present alloantigen efficiently. A conceptual model to improve their tumor immunogenicity," Proc. Natl. Acad. Sci. USA, Vol. 92, p. 8200-8204, (August, 1995).			
	C13	JOACHIM L. SCHULTZE, "Why Do B Cell Lymphoma Fail to Elicit Clinically Sufficient T Cell Immune Responses," Leukemia and Lymphoma, Vol. 32 ( No. 3-4), p. 223-236, (1999).			
	C14	SARAH E. TOWNSEND ET AL., "Tumor Rejection After Direct Costimulation of CD8+ T Cells by B7-Transfected Melanoma Cells," Science, Vol. 259, p. 368-370, (January 15, 1993).			
	C15	ANTONELLA VIOLA ET AL., "T Cell Activation Determined by T Cell Receptor Number and Tunable Thresholds," Science, Vol. 273, p. 104-106, (July 5, 1996).			
	C16	ANETTE GJORLOFF WINGREN ET AL., "T Cell Activation Pathways: B7, LFA-3, and ICAM-1 Shape Unique T Cell Profiles," Critical Reviews in Immunology, Vol. 15 ( No. 3&4), p. 235-253, (1995).			

Examiner Signature		Date Considered
--------------------	--	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.